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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,155	08/27/2004	Bryan E. GARNER	5233.012.NPUS00	5154

28694 7590 11/01/2006

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EXAMINER	
SHAW, AMANDA MARIE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/711,155	GARNER, BRYAN E.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10-13-2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,9-16 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,9-16 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed October 13, 2006. Applicant's arguments have been fully considered. This action is made final.

Claims 1-3, 7, and 9-16 are currently pending. Claims 1-3, 7, are 9-16 have been amended. Claims 37-41 are newly presented. Therefore Claims 1-3, 7, 9-16 and 37-41 will be addressed herein.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 1-3, 7, 9-16 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the instant case the specification does not provide support for the amendment to claim 1 which recites:

"A method for assessing the relative quanitity of viable microorganism of interest that is present and has been previously applied to a food product in the course of microbially treating the food product, said method comprising obtaining a liquid suspension sample comprising different microorganisms removed from a microbial-treated food product and which includes a substantial entirety of a previously applied and viable microorganism of interest from a known quantity of the microbial-treated food product and in which the different microorganisms are suspended in a liquid recovery media of known quantity; preparing a series of progressively dilute test samples by combining portions of the liquid suspension sample with a dilution liquid; incubating the series of progressively dilute test samples for a predetermined period of time under conditions conducive to growth of the microorganism of interest; conducting a PCR analysis on the series of progressively dilute test samples; and utilizing an estimation model to determine the concentration of the viable microorganism of interest present on the food product based on results of the PCR analysis".

It is noted that the applicant points to page 2-3 paragraphs 7-8, page 12 paragraphs 42-43, and page 13-50 paragraph 48 of the specification for support. It is further noted that the specification only contains 29 pages so it is unclear how pages 30-50 show support since there are only 29 pages. On page 3 paragraph 8 the specification states:

"The invention provides a method of quantifying a presence of a specific kind of probiotic microorganism in a sample of animal feed. The method includes: (a) dividing the sample into multiple portions; (b) culturing each portion of the sample under conditions suitable for growth of the specific kind of probiotic microorganism; (c) performing a polymerase chain reaction process by reacting each cultured portion of the sample successively with two oligonucleotide primers that selectively hybridize with nucleic acid of the specific kind of probiotic microorganism to produce a respective reaction product from each cultured portion of the sample; (d) detecting the presence or absence of a reaction product having a characteristic length from the reaction of each cultured portion of the sample; and (e) quantifying the presence of the specific kind of probiotic microorganism in the sample of material from the detected

presence or absence of a reaction product having a characteristic length from the reaction of each cultured portion of the sample".

This paragraph does not provides support for the claimed method because the specification does not teach a method with the recites steps as presented in claim 1. For instance there is no support for the step of "obtaining a liquid suspension sample comprising different microorganisms...", "preparing a series of progessively dilute test samples, and "utilizing an estimation model to determine the concentration of the viable....".

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 1-3, 7, 9-16 and 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 7, 9-16 and 37-41 are indefinite over the recitation of the phrase "relative quantity". This phrase in considered unclear because "substantial entirety" is not clearly defined in the specification and there is no art recognized definition for this phrase.

Claims 1-3, 7, 9-16 and 37-41 are indefinite over the recitation of the phrase "substantial entirety". This phrase in considered unclear because "substantial entirety" is not clearly defined in the specification and there is no art recognized definition for this phrase.

Claims 1-3, 7, 9-16 and 37-41 are indefinite over the recitation of the phrase "recovery media". This phrase in considered unclear because "recovery media" is not clearly defined in the specification and there is no art recognized definition for this phrase.

Claims 1-3, 7, 9-16 and 37-41 are indefinite over the recitation of the phrase "progressively dilute". This phrase in considered unclear because "progressively dilute" is not clearly defined in the specification and there is no art recognized definition for this phrase.

Claims 1-3, 7, 9-16 and 37-41 are indefinite over the recitation of the phrase "estimation model". This phrase in considered unclear because "estimation model" is not defined by the claim or the specification, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. While the specification teaches that the most probable number method can be used to estimate the amount of bacteria in sample, a complete definition for this term is not provided. It is unclear if the claims which recite "estimation model" are limited only to methods using the most probable number method or if additional methods meet this limitation. Since the specification only provides examples of what could be included by this phrase, these

teachings are not considered to be sufficient to provide a complete and fixed definition for the phrase "estimation model."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 1, 7, 12-15, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Begum et al (Molecular and Cellular Probes 1995).

Begum et al teach a method for the detection of Shiga like toxin producing E. coli (SLTEC) in ground beef which utilizes the polymerase chain reaction. In the method of Begum ground beef samples inoculated with (SLTEC) were diluted 10 fold in saline. The contaminated beef samples were then enriched at 37°C for four hours prior to PCR analysis. The PCR products were then visualized by agarose gel electrophoresis and membrane hybridization and a dig labeled DNA probe (Page 260 and 262). Table 3 shows a list of the strains that were used, the source of the strains that were used, the dilution that was tested, and how much was detected (Page 261). In the instant case the samples tested by Begum et al are being interpreted as samples of food that have been microbiologically treated because the beef samples were inoculated with SLTEC.

Additionally it is an inherent property that the beef sample would contain multiple types of microorganisms naturally.

Regarding Claim 7, Begum et al teaches that two PCR primers that are specific for the detection of SLT-II producing E. coli were used to amplify the DNA. These oligonucleotide primers hybridize to the nucleic acid sequence that is being detected and serve as a starting point for DNA amplification.

Regarding Claim 12 Begum et al teach that one way the amplification products were visualized is by hybridization with a dig labeled DNA probe that specifically hybridizes to the SLTEC (Page 262).

Regarding Claim 13, Begum et al teaches that two PCR primers that are specific for the detection of SLT-II producing E. coli were used to amplify the DNA. These oligonucleotide primers hybridize to the nucleic acid sequence that is being detected and serve as a starting point for DNA amplification. Begum et al further teach that one way the amplification products were visualized is by hybridization with a dig labeled DNA probe that specifically hybridizes to the SLTEC (Page 262).

Regarding Claim 15, Begum et al teach a method wherein the detecting of the presence or absence of a product includes performing electrophoresis (Page 260).

Regarding Claims 37 and 38 Begum et al teach the detection of Shiga like toxin producing E. coli (Page 259). This is considered a probiotic because it is listed in the specification that E. coli is considered a probiotic.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

Claims 2-3 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begum et al (Molecular and Cellular Probes 1995) in view of Ware (US Patent 5534271 Issued 1996).

The teachings of Begum et al are presented above in paragraph 4.

Regarding Claims 2-3 Begum et al do not teach that the sample being tested is a sample of animal feed that was taken from a feed pile and transported to a testing lab in way so that the sample at the lab is representative of the condition of the animal feed when the animal feed is to be consumed by animals. Additionally Begum et al do not teach that the sample of animal feed is taken from a feed pile at a location where the animal feed is to be consumed by animals.

However, Ware et al teaches a method wherein steer food containing L. acidophilus is tested. The test samples were taken from steer food and the testing was done to determine the amount of L. acidophilus in the samples. The testing was performed at the Silliker Laboratories in Chicago, IL (Column 11). Ware et al does not exemplify that the samples are taken from a feed pile at a location where the animal feed is to be consumed; however it would be obvious to one of ordinary skill in the art at the time the invention was made to have tested the sample under the same conditions of the animal feed when it is feed to animals because Ware et al teaches that L acidophilus is a very sensitive organism that is difficult to maintain in a viable state at ambient temperatures. Any shift in the temperature during the transportation of the sample from the animal feedlot to the laboratory could potentially kill the L. acidophilus during transportation thus yielding invalid results.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Begum et al so as to taken a sample of animal feed to a laboratory in order to perform testing for the added benefit of providing a sterile testing facility. Both Microbiology and Molecular biology assays are very sensitive and can be contaminated easily. By performing the assay in a FDA laboratory, steps are taken to ensure that contamination does not occur.

Regarding Claims 39-40, Begum et al do not teach a method wherein the specific kind of probiotic microorganism is Lactobacillus or L. acidophilus.

However Ware et al teach a method for detecting Lactobacillus acidophilus found in animal feed (Column 11).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Begum et al to detect and quantify Lactobacillus or L. acidophilus. This genus and species are routinely added to animal feed to increase milk and meat production. It would be beneficial to quantitate the amount of L. acidophilus is animal feed because Ware et al have shown that the amount of the probiotic in animal feed can change depending on the storage conditions (Column 11 and 12).

6. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begum (Molecular and Cellular Probes 1995) in view of Pahuski (US Patent 5587286 Issued 1996).

The teachings of Begum et al are presented above in paragraph 4.

Regarding Claims 9-10 Begum et al teach that the sample is divided into multiple portions by diluting the sample in saline (Page 260).

Begum et al do teach that the diluted samples are then further divided into multiple portions.

However, Pahuski et al teach that milk samples were diluted with saline and then 1m of 10 fold dilutions were pipetted into duplicate petri dishes thus the diluted samples were further divided (Example 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Begum et al so as to have divided the test sample into multiple portions by diluting the sample and dividing the

diluted sample into multiple portions as suggested by Begum for benefit of having multiple samples containing all different amounts of bacteria to test which can be used to further confirm the results and obtain information on the specificity of the assay.

Regarding Claim 11, Begum et al teach a method wherein the sample is divided into multiple portions by mixing the sample with saline (Page 260).

Begum et al do not teach that the fluid mixture is then divided into multiple portions.

However, Pahuski et al teach that milk samples were diluted saline and then 1m of 10 fold dilutions were pipetted into duplicate petri dishes thus the diluted samples were further divided (Example 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Begum et al so as to have divided the test sample into multiple portions by mixing with a liquid because this is an effective method of creating multiple portions containing the bacteria. The benefit of having multiple samples to test is that they can be used to further confirm the results and obtain information on the specificity of the assay.

7. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Begum et al (Molecular and Cellular Probes 1995) in view of Rust et al (Cattle Call 2000).

The teachings of Begum are presented above in paragraph 4.

Begum et al do not teach that the specific organism being detected in the animal feed is Lactobacillus LA-51.

However Rust et al teach that strain LA51 of Lactobacillus acidophilus can be added to animal feed. The addition of LA51 has been shown to help improve carcass adjusted average daily gain and feed conversion efficiency (Summary).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Begum et al to detect and quantify Lactobacillus LA51 in animal feed because it is an important microorganism that is routinely added to animal feed to improve carcass adjusted average daily gain and feed conversion efficiency.

8. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Begum et al (Molecular and Cellular Probes 1995) in view of Lucchini (Federation of European Microbiological Societies 1998).

The teachings of Begum et al are presented above in paragraph 4.

Regarding Claim 14 Begum et al do not teach a method wherein one PCR primer hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism.

However Lucchini et al teach that multiplex PCR was performed using four oligonucleotide primers. Two genus specific primers named LARNA5 and LARNA6 were used. These primers were specific to a conserved region of 248 bp within the 16S rRNA gene of lactobacilli. Two species-specific primers named APF3 and APF4 were also used. These primers were specific to L. gasseri.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Begum et al so as to have used one PCR primer which hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism for the added benefit of being able to distinguish between different species when more than one species is suspected of being present in the sample to be tested.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Begum (Molecular and Cellular Probes 1995) in view of DesRosier (US Patent 4868110 Issued 1989).

The teachings of Begum et al are presented above in paragraph 4.

Begum et al do not exemplify a method which further comprises using the most probable number method to determine the amount of bacteria in the sample.

However DesRosier et al teach that the most probable number test is one technique frequently used for estimating the amount of bacteria in food and water samples (Column 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Begum et al so as to quantified the amount of bacteria in the sample using the most probable number test as suggested by DesRosier for the benefit of using a procedure the utilizes liquid growth

media (because many microorganisms wont grow on solid media), permits greater flexibility in inoculum volume, and greater sensitivity at low microbial density (Column 2).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7, 9-16, and 37-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 16-17 of copending Application No. 10/711,156 in view of Ware and Rust. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both the present claims and the claims of '156 encompass methods for quantifying the

presence of a microorganism in a sample of food. The present claims differ from the claims of '156 in that the claims of '156 do not recite that the microorganism being detected is Lactobacillus, L. acidophilus, or Lactobacillus LA51 in samples of animal feed that are transported from an animal feedlot to a laboratory for culturing and using an oligonucleotide to detect the microorganism. However, Ware teaches a method for detecting L. acidophilus in steer food. The test samples were taken from steer food and the testing was performed at the Silliker Laboratories in Chicago, IL (Column 11). Ware et al does not exemplify that the samples are taken from a feed pile at a location where the animal feed is to be consumed, however it would be obvious to one of ordinary skill in the art at the time the invention was made to have tested the sample under the same conditions of the animal feed when it is feed to animals because Ware et al teaches that L acidophilus is a very sensitive organism that is difficult to maintain in a viable state at ambient temperatures. Any shift in the temperature during the transportation of the sample from the animal feedlot to the laboratory could potentially kill the L. acidophilus during transportation thus yielding invalid results. Additionally Rust et al teach that strain LA51 of Lactobacillus acidophilus can be added to animal feed. The addition of LA51 has been shown to help improve carcass adjusted average daily gain and feed conversion efficiency (Summary). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect and quantify Lactobacillus LA51 in animal feed because it is an important microorganism that is routinely added to animal feed to improve carcass adjusted average daily gain and feed conversion efficiency.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

RESPONSE TO ARGUMENTS

11. In the response filed October 13, 2006, Applicants stated that they have provided a terminal disclaimer to overcome the non statutory double patenting rejection. As of the date that this Office Action was created the Office has not yet received the terminal disclaimer. Accordingly, the rejection is maintained.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571)

272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful; the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER